



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/616,371	03/15/96	STAMLER, J	DOR96-03PA

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EXAMINER
CELSA, B

ART UNIT	PAPER NUMBER
1634	20

DATE MAILED: 09/08/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

file
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Advisory Action

Application No.
08/616,371

Applicant(s)
Stamler, J. S.

Examiner
Bennett Celsa

Group Art Unit
1654



THE PERIOD FOR RESPONSE: [check only a) or b)]

- a) ☐ expires _____ months from the mailing date of the final rejection.
- b) ☒ expires either three months from the mailing date of the final rejection, or on the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

- ☐ Appellant's Brief is due two months from the date of the Notice of Appeal filed on _____ (or within any period for response set forth above, whichever is later). See 37 CFR 1.191(d) and 37 CFR 1.192(a).

Applicant's response to the final rejection, filed on Aug 5, 1998 has been considered with the following effect, but is NOT deemed to place the application in condition for allowance:

☒ The proposed amendment(s):

- ☐ will be entered upon filing of a Notice of Appeal and an Appeal Brief.
- ☒ will not be entered because:
- ☒ they raise new issues that would require further consideration and/or search. (See note below).
 - ☒ they raise the issue of new matter. (See note below).
 - ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
 - ☒ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: See Attached.

- ☐ Applicant's response has overcome the following rejection(s):

- ☐ Newly proposed or amended claims _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claims.
- ☐ The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because:

- ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

☒ For purposes of Appeal, the status of the claims is as follows (see attached written explanation, if any):

Claims allowed: 4, 5, 9-14, 28, and 29

Claims objected to: _____

Claims rejected: 15-27

- ☐ The proposed drawing correction filed on _____ ☐ has ☐ has not been approved by the Examiner.
- ☐ Note the attached Information Disclosure Statement(s), PTO-1449, Paper No(s). _____.
- ☐ Other

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ADVISORY ACTION

Claims 4-5 and 9-29 are currently pending.

New claims 30-32 have not been entered.

The Amendment After Final has not been entered because:

1. They present additional claims without canceling a corresponding number of finally rejected claims.
2. In new Claim 30, the term “a preparation” raises issues of new matter, since the specification, although provide support for a “mixture” does not provide support for a preparation which is different in scope and is not equivalent to a mixture and there is no *ipsis verbis* support in the specification for “a preparation” nor has support for a preparation been provided.
3. New claims 31 and 32 are broader in scope than the previous composition claims of record and thus require additional search and consideration.
4. New claims 31 and 32 would necessitate the raising of an obvious double patenting rejection over claims 6-10 of copending 08/559,172 which has a common inventive entity and which is drawn to S-nitrosylated hemoglobin which is nitrosylated at 1 or more amino acid thiol moieties which represents a species within newly added claims 31 and 32.
5. New claims 31 and 32 additionally raise new matter considerations since the specification is drawn to a method of making a specific species of S-nitrosylated hemoglobin which is specifically nitrosylated without detectable oxidation of the heme as disclosed on pages 11 and 12 and in the original claim whereas the newly added claims are more generic in scope.

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- It is noted that the amendment of claims 15-16 and 18-23, if entered, would overcome the outstanding indefinite rejection of these claims.

- Applicant's arguments concerning the prior art rejections of record were considered but deemed nonpersuasive. The Declarations have already been found partially persuasive with respect to S-nitrosohemoglobin. With regard to the 102/103 rejection applicant has not sufficiently addressed the obviousness prong of the 103 rejection regarding the use of hemoglobin in conjunction with low molecular weight nitrosothios for therapies specifically disclosed by the Stamler reference. Applicant's arguments regarding mechanism is not persuasive insofar that the Stamler reference suggests the use of low molecular weight thiol or nitrosothiol alone or in conjunction with hemoglobin for regulating oxygen and NO, regardless of the mechanism. Applicant's citation of the Feelisch article which is purported to teach away from combining hemoglobin with low molecular weight nitrosothiols due to inhibition of vasorelaxant activity by hemoglobin is not persuasive to teach away from the Stamler et al. teaching of utilizing separate agents or combination of agents in order to attain a heightened effect regarding Oxygen and NO regulation which effects are not addressed in the Feelish article. With respect to the obviousness rejection over a combination of WO 93/09806 with Feola, Klatz and Hunter applicant's arguments of the references taken separately is not persuasive since the rejection is directed to a combination. Applicant fails to specifically address how the Examiner combined the aforesaid references in arriving at the obviousness rejection.

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General information regarding further correspondence

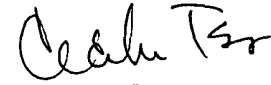
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Celsa whose telephone number is (703) 305-7556.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (703)308-0254.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Bennett Celsa


August 31, 1998


Cecilia J. Tsang
Supervisory Patent Examiner
Technology Center 1600